REMARKS

Claims 1-10 are pending in the instant application. Claim 1-10 have been rejected. Claims 1 and 4 have been amended. Support for these amendments is provided in the specification at page 1, lines 10-18, page 8, lines 27-29, and page 13, lines 7-11. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims under 35 U.S.C. § 102(b)

The Examiner has maintained the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by Kino et al. (WO 94/10982). Since this reference is in Japanese, in accordance with the Examiner's suggestions, Applicants have reviewed in detail the teachings of EP 0 669 128.

The Examiner has also maintained the rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Cheng et al.

Applicants respectfully traverse these rejections.

MPEP 2115 is clear; even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference.

Kino teaches a sustained release microsphere preparation containing a hydrophobic antipsychotic drug. In paragraph [0019] of EP 0 669 128 Kino teaches that the

particle size of the microspheres ranges from about 0.5 to about 400 μm, more preferably from about 0.5 to about 200 μM. Further, in paragraph [0020] of EP 0 669 128 Kino teaches that the microspheres can be made into sustained release injections by preparing an aqueous suspension together with a dispersing agent, a preservative and an isotonic agent or by preparing an oily suspension by dispersing the microspheres in a plant oil or in propylene glycol.

Similarly Cheng et al. teach haloperidol-loaded biodegradable poly(D,L-lactide-co-glycolide) microspheres with a theoretical mean particle size of about 0.8, 2 and 8 μm. They teach at page 204, second column that the microspheres can be suspended in an aqueous solution and then readily injected intramuscularly once every one to two months.

Such suspensions of micrometer sized particles are clearly structurally different from the implants of the present invention which are fabricated to be surgically implanted individually underneath the skin of a patient and removed if need be. See teachings throughout the specification and in particular at page 14 wherein surgical implantation of an individual implant of the present invention into an animal model is described. Such teachings make clear the intended use of the present inventions and

its structural differences compared to a suspension of microspheres.

In an earnest effort to advance the prosecution of this case and further distinguish structurally the surgical implant of the present invention from the microsphere suspensions taught by Kino and Cheng et al., Applicants have amended the claims to state that the biodegradable polymer or copolymer and haloperidol is fabricated into an implant via solvent casting and compression molding which is surgically implanted underneath the skin of a patient. Support for this amendment is provide at page 1, lines 10-18, page 8, lines 27-29, and page 13, lines 7-11 of the instant specification. This amendment is believed to make clear the structural differences between the surgical implant of the present invention and the sustained release injections of microsphere suspensions taught by Kino and Cheng et al.

Since both Kino and Cheng et al. teach structurally different devices to that of the instant claimed invention, they cannot anticipate the instant claimed invention. See MPEP 2115.

Withdrawal of these rejections under 35 U.S.C. 102(b) is therefore respectfully requested.

II. Rejection of Claims 1-6 under 35 U.S.C. 102(e)

The Examiner has maintained the rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al.

Arguments presented by Applicants in the response filed January 13, 2005 were not deemed persuasive as the Examiner suggests that the instant claims are not drawn to implants. Further, the Examiner suggests that the claims do not exclude a gel formulation.

Accordingly, in an earnest effort to advance the prosecution, Applicants have amended the claims to state that biodegradable polymer or copolymer and haloperidol is fabricated into an implant via solvent casting and compression molding. Further, the claims have been amended to be drawn to implants consisting essentially of biodegradable polymer or copolymer and haloperidol thus making clear that the implants are not gel formulations requiring a biocompatible solvent having low water miscibility that forms a viscous gel with the polymer as taught by Brodbeck et al.

Since Brodbeck does not teach the implants or methods for preparing the implants as claimed, this reference cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

III. Rejection of Claims 4-10 under 35 U.S.C. § 103

The rejection of claims 4-10 under 35 U.S.C. § 103 as being unpatentable over Cheng et al. has been maintained. Applicants arguments that Cheng does not teach solvent casting the haloperidol and biodegradable polymer solution as set forth in step b) of claim 4 or molding under compression into a surgical implant as set forth in step c) of claim 4 were not deemed persuasive as the Examiner suggests that Cheng teaches freeze drying which takes place under pressure. Further, the Examiner suggests that the application of pressure and the evaporation of the solvent results in solid product, which the compression in the instant claims leads to. Finally the Examiner suggests that Cheng discloses that the formulation is implantable thus indicating that the product would be made into a form that is suitable for implantation.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner suggestion that Cheng discloses that the formulation is implantable. Applicants have reviewed the teachings of Cheng carefully and do not see anywhere a teaching that the formulation is "implantable". Instead

Cheng et al. state at pages 203, 204, and 211 that the depot formulation is administered by intramuscular injection.

Further, as discussed in Section I, the product produced by the method of Cheng is structurally distinct from the implant of the present invention. The solid product produced by the method of Cheng is a microsphere with a theoretical mean particle size of about 0.8, 2 or 8 μm. Effective dosing of haloperidol via these microspheres is only achieved through injection of a suspension of these tiny microscopic particles.

In contrast, the present invention relates to a single solid implant which is surgically implanted underneath the skin of a patient. This is made clear in teachings through the specification and in particular at page 14 wherein surgical implantation of an individual implant of the present invention into an animal model is described. Applicants have also amended the claims in an effort to make clearer the structurally distinguishing characteristics of the present invention.

Cheng et al. neither teaches nor suggests a device with the structure of the claimed implant. Nor does Cheng et al. provide any reasonable expectation of success that an individual implant prepared by solvent casting and compression molding in accordance with the instant claimed invention would successfully deliver steady state

concentrations of haloperidol. Thus, this reference cannot establish a prima facie case of obviousness. See MPEP 2143.

Withdrawal of this rejection under 35 U.S.C. § 103 is therefore respectfully requested.

IV. Rejection of Claims 7-10 under 35 U.S.C. § 103

The rejection of claims 7-10 under 35 U.S.C. § 103 as being unpatentable over Brodbeck et al. (U.S. Patent 6,130,200) has been maintained.

Applicants respectfully traverse this rejection.

Arguments presented by Applicants in the response filed January 13, 2005 that Brodbeck does not teach or suggest the process of solvent casting and compression molding were deemed unpersuasive as the Examiner states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps is critical.

As already discussed in Section I, however, these process steps result in a surgical implant structurally distinct from the suspension of micrometer sized particles taught by Brodbeck. The claims have been amended to make clearer the structurally distinguishing features of the surgical implant of the present invention.

Brodbeck provides no teaching or suggestion of an individual implant which can be surgically implanted under the dermis to deliver steady states concentrations of

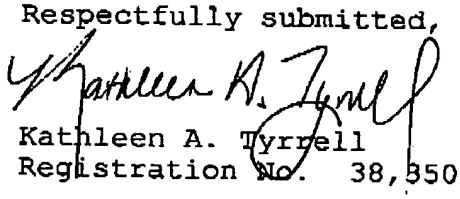
haloperidol to a patient. Further, the teachings of Brodbeck fail to provide any reasonable expectation of success with respect to the instant claimed implant. Thus, this reference cannot establish a prima facie case of obviousness with respect to claim 7-10 or claim 1. See MPEP § 2143.

Withdrawal of this rejection under 35 U.S.C. 103 is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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